UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

MEMORANDUM

DATE: February 22, 2012

SUBJECT: Efficacy Review for Sani-Cloth Germicidal Wipes;
EPA Reg. No. 9480-4;
DP Barcode: D396554

FROM: Thao Pham
Product Science Branch
Antimicrobials Division (7510P)

TO: Dr. Tajah Blackburn, Team Leader
Product Science Branch
Antimicrobials Division (7510P) 3/13/12

APPLICANT: Professional Disposables International, Inc.
Two Nice-Pak Park
Orangeburg, NY 10962-1376

FORMULATION FROM LABEL:

Active Ingredient(s)	% by wt
n-Alkyl (68% C_{12}, 32% C_{14}) dimethyl ethylbenzyl ammonium chlorides.....	0.25%
n-Alkyl (60% C_{14}, 30% C_{16}, 5% C_{12}, 5% C_{18}) dimethyl ethylbenzyl ammonium chlorides....	0.25%
Other Ingredients.....	99.50%
Total.....	100.00%

I BACKGROUND

The product, Sani-Cloth Germicidal Wipes (EPA Reg. No. 9480-4), is an EPA-approved disinfectant (bactericide, tuberculocide, virucide) and deodorizer for use on hard, non-porous surfaces in commercial, institutional, industrial, and hospital or medical environments. The applicant requested to amend the registration of this product to add new claims for effectiveness as a disinfectant against Avian influenza A (H5N1) virus and Swine influenza A (H1N1) virus. The label states that the product is effective in the presence of 5% blood serum. Studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121.

This data package contained a letter from the applicant's representative to EPA (dated November 17, 2011), EPA Form 8570-35 (Data Matrix), two studies (MRID 486608-02 and 486608-03), Statements of No Data Confidentiality Claims for both studies, and the proposed label.

II USE DIRECTIONS

The product is designed for disinfecting hard, non-porous surfaces, including: ambulance equipment, bathroom fixtures, bathtubs, bed railings, cabinets, carts, cash registers, chairs, changing tables, computers, counters, cribs, desks, diagnostic equipment, dialysis machines, diaper changing stations, diaper pails, doorknobs, endodontic equipment, examination tables, faucets, filing cabinets, floors, garbage cans, grocery cart child seats and handles, gym equipment, hampers, hand rails, handles, headsets, hospital equipment (e.g., gurneys, IV poles, operatory light switches, oxygen hoods, spine backboards, stethoscopes, stretchers, ultrasound transducers and probes), infant incubators, instrument trays, laboratory equipment, keyboards, patient monitoring equipment, patient support and delivery equipment, physical therapy equipment, railings, respiratory therapy equipment, seats, shower stalls, showers, sinks, tables, telephones, toilet seats, toilets, toys, trash cans, urinals, vanity tops, and work stations. The product label indicates that the product may be used on hard, non-porous surfaces, including: Formica, glass, glazed tile, metal, plastic, and stainless steel. Directions on the product label provide the following information regarding use of the product as a disinfectant: Use a wipe to remove heavy soil. Unfold a clean wipe and thoroughly wet surface. Treated surface must remain visibly wet for 2 minutes. Use additional wipe(s), if needed, to assure continuous 2-minute wet contact time. Let air dry.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Antimicrobial Products for Use on Hard Surfaces Using Pre-saturated or Impregnated Towelettes

Towelette products represent a unique combination of antimicrobial chemical and applicator, pre-packaged as a unit in fixed proportions. As such, the complete product, as offered for sale, should be tested according to the directions for use to ensure the product's effectiveness in treating hard surfaces. The standard test methods available for hard surface disinfectants and sanitizers, if followed exactly, would not closely simulate the way a towelette product is used. Agency guidelines recommend that a simulated-use test be conducted by modifying the standard test methods. Agency guidelines further recommend that instead of spraying the inoculated surface of the carrier, the product should be tested by wiping the surface of the carrier with the saturated towelette, and then subculturing the slides after a

specified holding time. Performance standards of the standard test methods must be met. These Agency standards are presented in EPA Pesticide Assessment Guidelines, Subdivision G, §91-2(h), Pre-saturated or impregnated towelettes; and the April 12, 2001 EPA Memorandum, Draft Interim Guidance for Non-Residual Sanitization of Hard Inanimate Food Contact Surfaces Using Pre-Saturated Towelettes.

Virucides

The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

Supplemental Claims

An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum.

IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID 486608-02 "Virucidal Efficacy of Pre-Saturated Towelettes for Hard Surface Disinfection, Virus: Avian Influenza A (H5N1) virus," for Super Sani Cloth 9480-4, by Kelleen Gutzmann. Study conducted at ATS Labs. Study completion date – May 4, 2009. Project Number A07541.

This study was conducted against Avian influenza A (H5N1) virus (VNH5N1-PR8/CDC-RG CDC #2006719965; obtained from the Centers for Disease Control, Atlanta, GA), using Rhesus monkey kidney cells (RMK cells; obtained from ViroMed Laboratories, Inc., Minneapolis, MD, Cell Culture Division) as the host system. Two lots (Lot Nos. TD-I-123-A and TD-I-123-B) of the product, Super Sani Cloth 9480-4, were tested according to ATS Labs Protocol No. NPP01121908.AFLU. The product was received ready-to-use, as a pre-saturated towelette. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 22.0°C at 14.1% relative humidity. For each lot of product, individual carriers were wiped with a saturated towelette with two wipes back and forth for a total of four passes. One towelette was used to treat one carrier (treated surface was not included). The carriers were allowed to remain wet for 2 minutes at 22.0°C. Following exposure, 2.00 mL of test medium was added to each Petri dish and each Petri dish was scraped with a cell scraper to re-suspend the contents.

The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 1% heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. RMK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for dried virus count, cytotoxicity, and neutralization (both product lots). Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

2. MRID 486608-03 "Virucidal Efficacy of Pre-Saturated Towelettes for Hard Surface Disinfection, Virus: Swine Influenza A (H1N1) virus," for Super Sani Cloth 9480-4, by Kelleen Gutzmann. Study conducted at ATS Labs. Study completion date – June 15, 2009. Project Number A07767.

This study was conducted against Swine influenza A (H1N1) virus (Strain A/Swine/Iowa/15/30; ATCC VR-333), using Rhesus monkey kidney cells (RMK cells; obtained from ViroMed Laboratories, Inc., Minneapolis, MN, Cell Culture Division) as the host system. Two lots (Lot Nos. TD-I-123-A and TD-I-123-B) of the product, Super Sani Cloth 9480-4, were tested according to ATS Labs Protocol No. NPP01042909.SFLU.1 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over a defined area on the bottoms of separate sterile glass Petri dishes. The virus films were dried for 22 minutes at 20.0°C at 53% relative humidity. For each lot of product, individual carriers were wiped with a saturated towelette with two wipes back and forth for a total of four passes. One towelette was used to treat one carrier (4 in^2). The carriers were allowed to remain wet for 2 minutes at 20.0°C. Following exposure, 2.00 mL of test medium was added to each Petri dish and each Petri dish was scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 1% heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. RMK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization (both product lots). Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

2. The proposed label claims do not support the use of the product, Sani-Cloth Germicidal Wipes, as a disinfectant against the following microorganisms on hard, non-porous surfaces in the presence of 5% blood serum for a 2-minute contact time:

Swine influenza A (H1N1) virus